

Message

From: Conneely, Eileen [Eileen_Conneely@americanchemistry.com]
Sent: 6/20/2018 1:50:30 PM
To: Thayer, Kris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ce4ae3f107749c6815f243260df98c3-Thayer, Kri]
CC: Gibbons, Catherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ac775a35a0945718edc7e02f50e6c12-Gibbons, Catherine]; Sasso, Alan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cb867519abc4dcea88149d12ef3e8e9-Sasso, Alan]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]; Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]; Ohanian, Edward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f119491e2ba8476381a39c57a456ac55-EOhanian]
Subject: RE: request to meet with IRIS staff concerning genomics dataset for Cr(VI)
Attachments: ACC EPA IRIS Correspondence re Cr6 Genomics Dataset 6 19 18.pdf

Dear Dr. Thayer,

Thank you for your response. It would be appreciated if the Cr(VI) research group would have adequate time to present at your protocol meeting.

Since the IRIS program has declined my request for a meeting, we are submitting the attached correspondence to the docket for the Cr(VI) IRIS assessment. The attached correspondence gives an overview of events relevant to the Cr(VI) genomics data, an explanation for the number of microarrays available through different online data repositories, and a general findings comparison between published analyses (i.e. genomics data analysis methods and standards have evolved over time and yet general findings have remained consistent despite varying approaches).

Please let me know if you have any questions.

Thank you,

Eileen Conneely

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From: Thayer, Kris [mailto:thayer.kris@epa.gov]
Sent: Monday, May 14, 2018 3:20 PM
To: Conneely, Eileen <Eileen_Conneely@americanchemistry.com>
Cc: Gibbons, Catherine <Gibbons.Catherine@epa.gov>; Sasso, Alan <Sasso.Alan@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Ohanian, Edward <Ohanian.Edward@epa.gov>
Subject: RE: request to meet with IRIS staff concerning genomics dataset for Cr(VI)

Thank you Eileen for your note.

As you can imagine with all the focus on scientific transparency at the Agency we really prefer to have science meetings occur in a public forum. Perhaps it's possible that multiple 10-minute slots could be combined to give the research group more time to present the overview of recent MOA publications?

The approach for considering toxicogenomic and other mechanistic evidence would be described in the systematic review protocol. The protocol will also present the screening results of studies for consideration in the assessment (included, excluded, tagged as potentially relevant supplemental information). Our Cr(VI) team is certainly familiar with publications from your MOA research group but are not able to discuss our interpretation of the science until we have a draft assessment for public comment.

Thanks for understanding and we will try to solidify the date of the meeting shortly.

Sincerely,

Kris

Kristina Thayer, Ph.D.
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From: Conneely, Eileen [mailto:Eileen_Conneely@americanchemistry.com]
Sent: Monday, April 30, 2018 3:31 PM
To: Thayer, Kris <thayer.kris@epa.gov>
Cc: Gibbons, Catherine <Gibbons.Catherine@epa.gov>; Sasso, Alan <Sasso.Alan@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Ohanian, Edward <Ohanian.Edward@epa.gov>
Subject: request to meet with IRIS staff concerning genomics dataset for Cr(VI)

Dear Dr. Thayer,

I appreciate your response. You noted that EPA expects to release a protocol on hexavalent chromium (Cr(VI)) this June or July and that EPA plans to convene a public webinar where EPA staff would summarize the protocol content and listen to public comment on the protocol. We appreciate the opportunity to present comments during the planned EPA webinar, but ten minutes would not be adequate to present an overview of the most recent MOA research publications. We hope that additional time will be granted. Please also let us know as soon as possible when you have set the date for the webinar, as many interested parties may have planned to be away on summer vacations.

Additionally, we have questions on what full implementation of systematic review entails for the EPA IRIS program, especially since we have heard that the IRIS program has not fully considered the large toxicogenomics dataset funded by the Hexavalent Chromium Panel. The MOA researchers communicated with Lyle Burgoon, formerly at EPA, from 2014 – 2016 concerning the Cr(VI) genomics dataset, and we would like to present an overview of events relevant to the Cr(VI) genomics data, an explanation for the number of microarrays available through different online data repositories,

and a general findings comparison between published analyses (i.e. genomics data analysis methods and standards have evolved over time and yet general findings have remained consistent despite varying approaches).

To ensure that all of this important genomics data is being considered in the assessment process, we would like to schedule a meeting as soon as possible with you and the IRIS staff working on the Cr(VI) assessment.

Sincerely,

Eileen Conneely

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From: Thayer, Kris [<mailto:thayer.kris@epa.gov>]
Sent: Thursday, March 29, 2018 5:08 AM
To: Conneely, Eileen <Eileen_Conneely@americanchemistry.com>
Cc: Gibbons, Catherine <Gibbons.Catherine@epa.gov>; Sasso, Alan <Sasso.Alan@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Ohanian, Edward <Ohanian.Edward@epa.gov>
Subject: RE: Draft IRIS Assessment of Hexavalent Chromium (Chromium VI)

Eileen,

Thanks again for reaching out. We appreciate your sharing the list of recent publications.

We anticipate releasing a protocol on hexavalent chromium (Cr6) for public comment this June-July timeframe. The protocol will summarize the rationale for conducting the assessment, describe screening criteria to identify relevant literature, outline the approach for evaluating study quality, describe the process of evidence synthesis/integration, and dose-response methods. The protocol is a new document for the IRIS Program developed as part of its full implementation of systematic review (see presentation materials for the NAS Workshop "[Review of Advances Made to the IRIS Process](#)"). Obviously, the chromium assessment has been underway for some time now and release of this protocol should not be construed as a re-start. Rather, we are releasing the protocol so that the chromium assessment has similar public engagement steps as assessments started more recently. The protocol will include the list of studies currently included in the assessment.

Given the high level of interest in the IRIS hexavalent chromium assessment, we are planning to convene a public science webinar concurrent with the public comment period on the protocol. The format of this webinar would be a presentation by EPA staff summarizing the protocol content, followed by a public comment session where the Hexavalent Chromium Panel could present the overview suggested in your note below during a 10-minute public comment period. It may be possible to extend the length of the oral comment period depending on the number of registered speakers. EPA scientists would respond to questions of clarification but would not be discussing scientific interpretation of the evidence at this point in our process. Written materials could also be submitted as part of the public comment period.

We understand you may have questions on what full implementation of systematic review entails and how it integrates with the IRIS process. Although these topics are covered in the NAS presentation materials, we would be happy to schedule a meeting if you would like to discuss further.

Sincerely,

Kris

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From: Conneely, Eileen [mailto:Eileen_Conneely@americanchemistry.com]
Sent: Thursday, March 22, 2018 8:24 PM
To: Thayer, Kris <thayer.kris@epa.gov>
Cc: Gibbons, Catherine <Gibbons.Catherine@epa.gov>; Sasso, Alan <Sasso.Alan@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Ohanian, Edward <Ohanian.Edward@epa.gov>
Subject: Re: Draft IRIS Assessment of Hexavalent Chromium (Chromium VI)

Dear Dr. Thayer,

Please see the attached letter written on behalf of the Hexavalent Chromium Panel of the American Chemistry Council requesting a stakeholder meeting with IRIS staff to present an overview of the most recent publications by the MOA study researchers, and to review important information relevant to the Cr(VI) genomics dataset that was communicated to Dr. Lyle Burgoon prior to his departure from EPA.

Thank you,

Eileen Conneely

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